Remarks

Claims 1-7 were pending in this application. Applicant has amended the specification to update the status of applications to which the instant application claims priority, as per Examiner's request. Claims 1, 6 and 7 have been amended. Applicants' note no prior art rejections were cited against Claim 7. New Claims 8-16 have been added. In the Office Action, the Examiner has rejected claims 1-6 under 35 U.S.C. §103(a) as unpatentable over U.S. Patent 4,959,002 to Pleasant (hereinafter "Pleasant") in view of IBM Technical Disclosure Bulletin entitle "Use of High Precision Silicon Molds for Replicating Microelectronic Packaging Structures" (hereinafter "the Technical Disclosure"). The applicant notes that there are no 35 U.S.C. §102 rejections upon any of the claims 1-7.

Applicants discussed the lack of 35 U.S.C. §102 or §103 rejections of Claims 7 on February 18, 2005 in a telephone call with Examiner Heckenberg. Applicants would like to thank Examiner Heckenberg for taking the call and clarifying the rejection. Applicants are proceeding with this amendment on the basis that there are only 35 U.S.C. §112, second paragraph rejections on Claim 7 and that any 35 U.S.C. §102 or §103 rejections upon Claim 7 would be addressed in the next rejection. Should the Examiner pose 35 U.S.C. §102 or §103 rejections upon Claim 7, it is presumed that the next action would be Non-Final per MPEP §706.07(a).

Applicants have amended Claims 1, 6 and 7 to clarify how the mold is structured with respect to recesses and cavities, per the suggestion of the examiner. As discussed below, new Claims 8-16 have been added.

As an initial matter, it should be noted that the present invention is directed to a mold for use in injection molding micro- and sub-micron needle structures with sharp edges for use in medical devices. The mold of the present invention has several advantages over prior art methods of forming needles, which are achieved by structures that are not obvious in light of the prior art. These advantages include: cost savings, good reproducibility (including sharp edge formation), high resolution of detail, and elimination of mold-release requirements to provide for sterile product. Aspects of the invention provide for a mold to produce sharp contours on medical devices which form

cutting and scraping edges. These benefits are unachievable using conventional methods of manufacture for micro scale devices, as described in the instant specification: embossing, stamping, etching or masking methods. In addition, the applicants have taught a mold structure which supports the components fabricated from silicon so that stresses on the silicon parts, and thus mold breakage, are minimized.

Claim Rejections under 35 USC § 112

The Examiner has rejected Claims 1-7 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Accordingly, applicant has amended Claims 1 and 7 to clarify where the silicon mold member resides. Applicants wish to note that Claim 7 has not been amended in view of the prior art, but to clarify the location of the silicon mold member. As the examiner has pointed out, the mold recess holds the silicon mold member, which has features of interest which face the mold cavity. In addition, Claim 6 has been amended to clarify that it is the needle forming recesses which have a specific spacing.

Claim Rejections under 35 USC 103

The Examiner has rejected claims 1-6 under 35 U.S.C. §103(a) as unpatentable over Pleasant in view of the Technical Disclosure.

Pleasant discloses improved quick-changeover cavity inserts for mold tooling. Each insert comprises a generally cylindrical, stepped body provided with a pair of circumferentially extending clamping grooves and a circumferentially extending liquid cooling or heating channel. Specifically designed retainers are described which retain the mold inserts within the mold. The mold insert of Pleasant must withstand the forces required for locking the mold insert into the mold frame. Pleasant does not achieve micro molded parts or sharp edges as are formed by the device of the instant invention. Pleasant does not teach or suggest the need for a specific structure to produce highly accurate sharp edges.

Allegedly, the Technical Disclosure discloses molds and dies made from silicon. Although Figures 3-6 in the Technical Disclosure may appear to show molds, they, in fact, show dies for stamping and embossing. In fact, the "mold" disclosed in the Technical Disclosure (as shown in Fig 2 only) is not a mold insert but an open cavity or embossing tool. It appears that the "mold" system of the Technical Disclosure is an "Open System" or a simple trough, wherein the mold insert is used for pouring the liquid molding material onto the mold insert, or used as a "tool" to impart its shape on a work piece, in the case of dies. There may be a lateral border for shaping the vertical sides of the liquid material but there is absolutely no mold consisting of two mold sections. The 'mold' as described in the Technical Disclosure would not be suitable for injection molding since it is an open trough and the mere addition of the teachings of Pleasant does not enable a structure which would allow injection molding, or moreover, the injection molding of sharp edges as in the present invention. In summary, the Technical Disclosure reference is an embossing system, which certainly does not lead to a closed mold system, even in combination with the teachings of Pleasant.

There is no suggestion in either reference that an open or closed mold system may indeed produce needles of sufficient size, shape and sharpness. In fact, it is common practice in molding to eliminate sharp corners and edges in molding systems. The references cited by the examiner merely show the production of small features, which are conducive to molding, such as bumps and depressions, and molds having sub-assemblies which may be inserted and removed. None of the references cited by the examiner disclose or suggest systems to produce shapes of sufficient sharpness to produce cutting features required for needles. In contrast, the present invention utilizes a mold consisting of two mold sections that may be moved to open and close the mold, forming a closed mold cavity. As shown in Fig 1 and 2 of instant application the mold systems of the present invention produce a sharp edge (20), which flows in two dimensions on the needle, and is not shown in any of the references alone or in combination. In fact, the references cited all have long linear edges, which are not 'sharp,' some of which traverse the entire length of the part in the form of a line. Furthermore, none of the references alone or in combination cited disclose or suggest a sharp scraping edge of the form of the invention. Therefore, the combination of Pleasant and the Technical Disclosure do not

produce the claimed invention, as the configuration of the mold sections, mold recesses and resultant parts are not the same. The Examiner should note, according to MPEP §2143.02, a statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to modify the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). See also *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000). The examiner may not appropriately rely on "the level of skill in the art" to provide the suggestion to make modifications to the Pleasant device with the features of the Technical Disclosure to produce the instant invention.

The Examiner specifically rejects claims 2 and 6 by relying on the rule that discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art by citing *In re Boesch*, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980); and *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Since neither reference discloses any operable range of shape and dimensions for the recesses, it is improper for the Examiner to rely on this rule for an obviousness rejection.

The Examiner has not shown that Pleasant and the Technical Disclosure teaches a plurality of recesses 5-250 microns deep for forming needles having at least one sharp edge as required by Claims 2 and 6. If indeed there were operable ranges disclosed in Pleasant and the Technical Disclosure, there are exceptions to this rule, one of which is noted in *In re Sebek*, 465 F.2d 904, 907, 175 USPQ 93, 95 (CCPA 1972):

> *"However, while it may ordinarily be the case that determination of optimum values for parameters of a prior art process would be at least prima facie obvious, that conclusion depends upon what the prior art discloses with respect to those parameters."*

The Examiner has failed to point to any disclosure or suggestion in Pleasant and the Technical Disclosure, merely citing examples directed to a mold insert system and use of silicon as a mold construction material. In fact, neither reference teaches or

suggests any range of dimensions for the molding recesses, the pattern of molding recesses, or for any features which may be molded other than to utilize the term "micro." Furthermore, the shape and design of the pattern of molding recesses, as in Claim 6, is not suggested by any of the references. The examiner has not established, *why* the selection of silicon as a mold material would have suggested the claimed shape and dimensions of the silicon based mold. For the foregoing reasons, the examiner has not established a prima facie case of obviousness in view of Pleasant and the Technical Disclosure for claims 2 and 6.

Furthermore, it would not have been obvious to simply adapt the macro-level device of Pleasant to a process for producing molded needle devices with micron and sub-micron features. Pleasant does not teach or disclose advantages as mentioned above, and molding of needle devices as in the instant invention cannot be achieved by Pleasant alone or in combination with the Technical Disclosure; therefore, the invention is non-obvious over the teachings of Pleasant in view of the Technical Disclosure. For all the reasons stated above, the combination of Pleasant and the Technical Disclosure do not produce the instant invention as claimed. Furthermore, the Applicants contend the record does not appear to establish the requisite motivation for combining Pleasant and the Technical Disclosure, as obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In the case of the present application, the suggestion to combine the teachings of Pleasant with the teachings of the Technical Disclosure is not present.

New Claims

New claims 8-16 have been added to further define aspects of the invention, which are fully supported by the instant specification. Accordingly, no new matter has been added. New independent claim 8 has similar elements and structure as original Claim 1 but in addition recites the limitations of an operable mold cavity having an open

and closed state. For all of the reasons discussed previously, none of the references, alone or in combination, teach or suggest a mold according to the present invention. Without discussing each in detail, it will be appreciated that the claims depending from Claim 8 recite additional features that are not taught or suggested by the prior art. Claim 16 includes limitations on Claim 7 as to how the mold device is structured.

Conclusion

In view of the Remarks above, applicant respectfully submits that Claims 1-16 are in condition for allowance, and respectfully requests that the Examiner earnestly reconsider his rejections of the present application. Applicant hereby authorizes the Commissioner to charge the fees necessary in connection with this Response and any other fees necessary in connection with this application, to Deposit Account Number 02-1666.

Applicant respectfully requests that the Examiner enter the amendments and consider the remarks made herein. Consideration and prompt allowance of the claims are respectfully submitted.

Any questions concerning this application or amendment may be directed to the undersigned agent of applicant.

Respectfully submitted,

Dated: March 8, 2005.

By: _____

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